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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/816,377 | 04/01/2004 | Magnus Bolmsjo | 211.315 | 6188 |
| 7590 03/06/2006 | | | EXAMINER | |
| John R Ley LLC 5299 DTC Boulevard Suite 610 Greenwood Village, CO 80111-3327 | | | GIBSON, ROY DEAN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3739 | |

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/816,377 | Applicant(s) BOLMSJO, MAGNUS | |
| | Examiner Roy D. Gibson | Art Unit 3739 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-108 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-62 and 84-108 is/are allowed.
- 6) ☒ Claim(s) 63-74 and 80 is/are rejected.
- 7) ☒ Claim(s) 75-79 and 81-83 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>4/1/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 63-69, 71 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Behl (5,222,938). Behl discloses a catheter insertable into a urethra for performing therapeutic heat treatment comprising:

an antenna (an alternative source to the coil # 110 of Figure 11 as disclosed in col. 7, lines 20-22);

an expandable reservoir (inflatable balloon # 112) filled by a heat conductive medium; and

a channel (Figure 5, # 60) extending within the catheter from a position at an exterior of the tissue and communicating with the expandable reservoir (col. 4, lines 58-68, col. 9, lines 33-50 and col. 11, line 6-col. 12, line 17).

Note that the functional language of the claim directed toward the treatment of the prostate or bladder neck is “intended use only” and that the catheter of Behl is fully capable of being used in this manner.

Further to claims 66-69, Behl discloses a feed cable and a separate cooling channel extending along the feed cable through which perfusion fluid can be supplied through the proximal end of the catheter to the perfusion port (83).

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Further to claim 71, Behl discloses: the system will be provided for controlling the temperature to which the thermally conductive medium is heated by the heating means. Such a temperature control system may comprise a feedback controller where a temperature sensing element (typically a thermocouple or thermistor) is mounted on the catheter at a location chosen to accurately measure the heated environment surrounding the catheter, and the energy delivered to the heating means is regulated based on the measured temperature of the medium (col. 7, lines 28-37).

Further to claim 80, in the alternative embodiment of a MW antenna used in place of a heating coil (110), inherently a MW generator would be supplied as well.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Behl.

Behl discloses only one temperature sensor as above in the rejection of claim 71, but the examiner maintains that it would have been obvious to one of ordinary skill in the art of medical catheters to add an additional temperature sensor positioned within the reservoir to provide even more accurate temperature of the inflation medium as required. Such use of multiple sensors is well known in the art.

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Claims 72-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Behl. in view of Hascoet et al. (WO 94/01177). Behl fails to disclose a carrier and associated temperature probe(s) which can be extended from the catheter to penetrate and measure the temperature of the prostate. But, Hascoet et al. disclose a device comprising: a heating means (Figure 8, microwave antenna # 856) for local heating of the prostate tissue; a urological catheter (850) completely closing the heating means; a first temperature sensing means (912) connected to a carrier (guiding means # 914 including the sheath of the optical fiber), the first carrier being movable through and radially out a wall of the catheter and having a pointed tip adapted for insertion into the prostate tissue (p. 14, 2nd and 3rd paragraph). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Behl, as taught by Hascoet, to provide accurate temperature within the tissue of the organ being treated.

Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over Behl/Hascoet et al. as applied to claims 72-73 above, and further in view of Brucker (5,500,012). Hascoet et al. further teach a plurality of temperature sensors comprising strands of optical fibers arranged at various location (p. 4, 2nd P and p. 14, last P). But, Hascoet et al. lack the specific disclosure that the plurality of temperature sensors are positioned along a distal end of the carrier to determine the temperature at various depths in the tissue. However, Brucker et al. disclose a catheter (100) for cardiac ablation comprising a carrier (Figure 10, wire # 128) having a plurality of temperature

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sensors (for example, # 132 & 134) at its distal end for measuring the temperature at various depths in the tissue into which it is inserted (col. 8, lines 37-49).

Therefore, at the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the device of Behl/Hascoet et al., as taught by Brucker et al., as an alternative equivalent means of measuring the temperature at various depths by positioning the plurality of sensors along a distal end of the carrier. Note that Brucker et al. teaches the equivalence of sensors such as thermistors, thermocouples or optical fibers. Also note that a third sensor would be obvious if required by the procedure as dictated by the size of the tissue being treated. In addition see patent law recited in PMEP 2144.04, VI B regarding the "duplication of parts".

Allowable Subject Matter

Claims 1-62 and 84-108 are allowed.

Claims 75-79 and 81-83 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

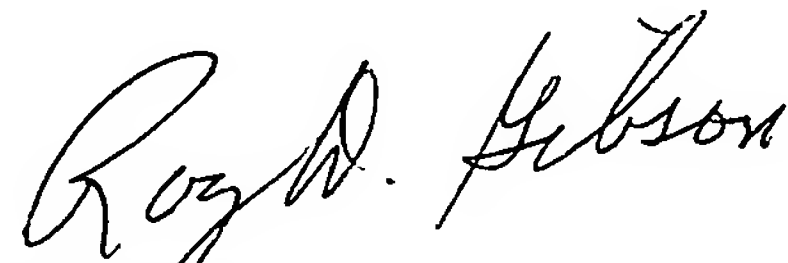
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on Tu-Th, 7:30 am-4:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Roy D. Gibson
Primary Examiner
Art Unit 3739

March 2, 2006